



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/551,574

10/03/2005

Nicholas D. P. Cosford

MS0037YP

3830

210 7590 07/11/2007
MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER

YOUNG, SHAWQUIA

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

07/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/551,574

Applicant(s)

COSFORD ET AL.

Examiner

Shawquia Young

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-18 are currently pending in this application. In a previous Office Action, the Examiner restricted Applicants' claimed invention into three groups and Applicants elected Group I, further limited such that A is C₀₋₄alkyl, B is C₀₋₄alkyl, X is aryl, W is C₀₋₆alkylheteroaryl, Y is heteroaryl and Z is absent wherein each of the above variables are unsubstituted or substituted as described in claim 1, in a response filed on April 11, 2007. However, the Examiner is unable to search Group I because of the vastness of claimed subject matter and is reissuing a supplemental restriction requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Claims 1-18 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Art Unit: 1626

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,...."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I claim(s) 1-14 (inpart), are drawn to a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is pyridine; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylpyridine, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; **R**¹¹, **R**¹² and **R**¹³ are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 546.

Group II claim(s) 1-14 (inpart), are drawn to a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is pyridine; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylphenyl, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted

Art Unit: 1626

as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; R^{11} , R^{12} and R^{13} are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 546.

Group III claim(s) 1-14 (inpart), are drawn to a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is pyridine; **A** is C_{0-4} alkyl; **B** is C_{0-4} alkyl; **Z** is absent; **W** is C_{0-6} alkylthiazole, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; R^{11} , R^{12} and R^{13} are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 546.

Group IV claim(s) 1-14 (inpart), are drawn to a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is pyridine; **A** is C_{0-4} alkyl; **B** is C_{0-4} alkyl; **Z** is absent; **W** is C_{0-6} alkylpyrimidine, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; R^{11} , R^{12} and R^{13} are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 544.

Group V claim(s) 1-14 (inpart), are drawn to a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is thiazole; **A** is C_{0-4} alkyl; **B** is C_{0-4} alkyl; **Z** is absent; **W** is C_{0-6} alkylpyridine, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; R^{11} , R^{12} and R^{13} are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 546.

Group VI claim(s) 1-14 (inpart), are drawn to a compound represented by

Art Unit: 1626

formula (I), wherein **X** is a phenyl group; **Y** is thiazole; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylthiazole, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; **R**¹¹, **R**¹² and **R**¹³ are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 548.

Group VII claim(s) 1-14 (inpart), are drawn to a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is thiazole; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylpyrimidine, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; **R**¹¹, **R**¹² and **R**¹³ are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 544.

Group VIII claim(s) 15-18 (inpart), are drawn a method of using a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is pyridine; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylpyridine, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; **R**¹¹, **R**¹² and **R**¹³ are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 514.

Group IX claim(s) 15-18 (inpart), are drawn to a method of using a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is pyridine; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylphenyl, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; **R**¹¹, **R**¹² and **R**¹³ are as defined in claim excluding heteroaryl or

Art Unit: 1626

heterocycloalkyl groups, classified in various subclasses of class 514.

Group X claim(s) 15-18 (inpart), are drawn to a method of using a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is pyridine; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylthiazole, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; **R**¹¹, **R**¹² and **R**¹³ are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 514.

Group XI claim(s) 15-18 (inpart), are drawn to a method of using a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is pyridine; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylpyrimidine, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; **R**¹¹, **R**¹² and **R**¹³ are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 514.

Group XII claim(s) 15-18 (inpart), are drawn to a method of using a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is thiazole; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylpyridine, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; **R**¹¹, **R**¹² and **R**¹³ are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 514.

Group XIII claim(s) 15-18 (inpart), are drawn to a method of using a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is thiazole; **A** is C₀₋₄alkyl; **B** is C₀₋₄alkyl; **Z** is absent; **W** is C₀₋₆alkylthiazole, where each of **A**, **B**, **X**, **Y**, and **W** are

Art Unit: 1626

unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; R^{11} , R^{12} and R^{13} are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 514.

Group XIV claim(s) 15-18 (inpart), are drawn to a method of using a compound represented by formula (I), wherein **X** is a phenyl group; **Y** is thiazole; **A** is C_{0-4} alkyl; **B** is C_{0-4} alkyl; **Z** is absent; **W** is C_{0-6} alkylpyrimidine, where each of **A**, **B**, **X**, **Y**, and **W** are unsubstituted or substituted as defined in claim 1 excluding heteroaryl or heterocycloalkyl groups; R^{11} , R^{12} and R^{13} are as defined in claim excluding heteroaryl or heterocycloalkyl groups, classified in various subclasses of class 514.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, **this list is not exhausted**, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same. **If applicant is unable to elect a single invention, applicant may instead choose to elect a specific compound and examiner will attempt to group it.** The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art (See, Example 78. WO 03/063576 A2, for example). The compounds claimed contain a pyrrole moiety, which does not define a

Art Unit: 1626

contribution over the prior art. The compounds vary in classification and when taken as a whole result in vastly different compounds. Accordingly, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

Advisory of Rejoinder

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B)

Art Unit: 1626

elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.EP 821.04 and *In re Ochiai*, 71 F.3d 1565, 37

USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims

Art Unit: 1626

commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:00 AM-2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

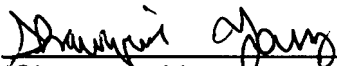
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1626

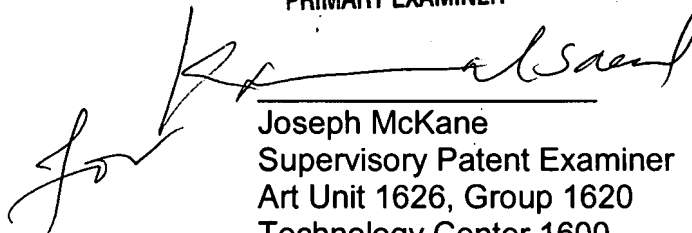
you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER



Shawquia Young
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600



Joseph McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600